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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,837	11/19/2001	Yi-Fen Tsai	05204-018002	9375
26161	7590	04/20/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 04/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/988,837

Applicant(s)

TSAI ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/560,873.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date November 19, 2001.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Amendment Entry & Claim Status***

The preliminary amendment filed on November 19, 2001 has been acknowledged and entered.

Claims 1-9 were cancelled. Claims 10-22 are being considered.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Taiwan, China on 28 April 1999. It is noted, however, that applicant has not filed a certified copy of the above application as required by 35 U.S.C. 119(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 lacks a positive detectable step indicative of the presence or quantity of the cells being assayed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 5,076,950).

Ullman teaches a method of assay cell surface antigens such as a blood group antigen (A, B, AB, O, D, etc) or an HLA antigen (see col. 4, lines 49-50). Such method comprises the steps of providing a sample containing said cell; providing a first complex comprising magnetic particles to which are bound a specific binding member to the analyte of interest (cell surface antigen); providing a second complex comprising a signal producing system which includes a labeled specific binding member and a magnetic field as a magnetic support; mixing said sample with said first and second complexes to form a third complex; providing a magnetic support to immobilize said third complex; separating said third complex from said sample in the presence of said magnetic support (magnet); and generating a signal from said third complex (see col. 15, lines 50-55; col. 17, lines 35-42; col. 18, lines 14-70). Specific binding members include IgG protein (monoclonal antibody), antigen/antibody pair. The diameter of the magnetic particles is from about 5 nm to 1 micron. The magnetic material is ferrite (see col. 10, lines 14-33). The signal producing system includes at least one catalyst, usually an enzyme, and at least a substrate, a radioactive substance, a fluorescer or a chemiluminescer. (see col. 9, lines 3-45). Enzymes include galactose oxidase, hydrogen peroxidase, horse radish peroxidase, glucose oxidase, beta-galactosidase. The signal producing system can include at least one catalyst, usually an enzyme, and at least one substrate or a plurality of enzymes and substrates, where the substrate of one enzyme is the product of the other enzyme. (see col. 9, line 38-col. 10, line 4). The

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method further comprises a step of washing the sample with a buffer, (and removing the buffer) after separation. (see col. 19, example 2). Analytes can be non-magnetic particles such as leukocytes (see col. 7, lines 30-45).

Claims 10-12, 15, 17, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Liberti et al. (US 5,466,574).

Liberti teaches an enzyme-labeled immunoassay comprising mixing the sample with reagents such as magnetic particles having a biospecific receptor such as a particular antibody for binding with a cell surface antigen and an enzyme-linked receptor that is also specific for the antigen. A magnetic field (magnetic support) is applied to separate the bound from unbound. The presence or quantity of cell-surface antigen is then determined by generating a signal from the label (col. 13, line 45-col. 14, line 8). Monoclonal antibodies are used as receptors (see col. 10, lines 10-16). Labels include fluorescent, chemiluminescent, enzymes and substrates. (see col. 13, lines 25-27).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (US 5,076,950).

Ullman has been discussed above.

However, Ullman fails to teach the specific analyte to be HLA B27.

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It would have been obvious to one of ordinary skills in the art to assay specific cell surface antigens such as HLA B27 or other HLA (human leukocyte antigens) using the method of Ullman since Ullman teaches that the sample contains human leukocytes. Depending on the particular diseases, which are being tested for, related specific HLA's are assayed. Among these diseases is ankylosing spondylitis, which is associated with HLA B27.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (US 5,076,950) in view of Liberti (US 6,013,532).

Ullman has been discussed above.

However, Ullman fails to teach using a common HLA CD45.

Liberti '523 teaches a method of manipulation of cells subsequent to mixing magnetic colloids with a sample of cells containing a specific target cell. Such mixture of magnetic colloids and target cells is then labeled with a Fitc CD45 cell marker. The cells were washed in buffer. Fluorescently labeled cells were observed (see examples 1-2).

It would have been obvious to one of ordinary skills in the art to use CD45 as a cell marker taught by Liberti in the method of assaying for cell surface antigen taught by Ullman since both methods are using magnetic particles as means for immobilization of target cells; and labels such as fluorescent. Since, CD45 is known for cell-marker, it would have been obvious to one of ordinary skills in the art to use it to label cells in assay for cells such as cell surface antigens.

### ***Conclusion***


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
April 14, 2004

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641